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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 18

Serial Number: 09/056072
Filing Date: 4/7/98
Appellant(s): Bazin et al.

Raymond J. Lillie
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's Brief on appeal filed 6/8/00 (Paper No. 17).

The text of those sections of Title 35 U.S.Code not included in this appeal can be found in a previous Office action herein.

(1) Real Party of Interest.

A statement identifying the real party of interest in contained in the Brief.

(2) Related Appeals and Interferences Identified.

A statement identifying that no related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the Brief.

(3) Status of Claims.

The statement of the status of claims contained in the Brief is incorrect.

Upon reconsideration, the previous rejection of claims 34 and 42 under 35 U.S.C. § 112, second paragraph, with respect to the recitation of "chimeric" has been withdrawn.

This appeal involves claims 30-44.

(4) Status of Amendments After Final.

The appellant's statement of the status of amendments after final rejection contained in the Brief is correct.

(5) Summary of Invention.

The summary of invention contained in the Brief is correct.

(6) Issues.

The appellant's statement of the issues in the Brief is incorrect.

Upon reconsideration, the previous rejection of claims 38 and 42 under 35 U.S.C. § 112, second paragraph, with respect to the recitation of "chimeric" has been withdrawn.

(7) Grouping of Claims.

Appellant's Brief includes a statement that claims do not stand or fall together, as set forth in 37 CAR 1.192(c)(7) and (c)(8) for the reasons set forth in the Arguments. See Brief and the rebuttal herein.

(8) Claims Appealed.

The copy of the appealed claims contained in the Appendix to the Brief is correct.

(9) Art of Record.

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

A) Bazin et al., U.S. Patent No. 5,730,979.
B) Bazin et al., U.S. Patent No. 5,951,983.
Previously cited as copending USSN 08/477,989 in a double patenting rejection.
C) Bromberg et al., Transplant. 51: 219-225, 1991.,
D) Chavin et al., Transplant. 54: 286-291, 1992.
E) Faustman, U.S. Patent No. 5,283,058.
F) Giorgi et al., Transplant. Proc. 36: 293 - 297, 1983.
G) Guckel et al., J. Exp. Med. 174: 957-867, 1991.
H) Hafler et al. J. Immunol. 141: 131-138, 1988.
I) Newman et al., U.S. Patent No. 5,658,570.
J) Queen et al., U.S. Patent No. 5,530,101.
K) Third International Workshop and Conference on Human Leukocyte Differentiation Antigens in Oxford, September 21-26, 1986, page 149.
L) Thurlow et al., Transplant. 36: 293-297, 1983.
M) Xia et al., in Rat Hybridomas and Rat Monoclonal Antibodies, Ravoet et al. (Ed.), CRC Press Inc. Boca Raton, Florida, 1990, pages 309-322.

(10) Grounds of Rejection.

The following ground(s) of rejection are applicable to the appealed claims.

Rejection Under 35 U.S.C. § 102(b)

Claims 30-32, 35-40 and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Xia et al. (Rat Hybridomas and Rat Monoclonal Antibodies, 1990). Xia et al. teach the LO-CD2a-specificity, including hybridomas and methods of making said antibodies and hybridomas of the instant invention (see entire document and page 312 for example). Although the reference is silent about a pharmaceutically acceptable carrier per se, the storage and use of the LO-CD2a antibody in pharmaceutically acceptable carriers such as PBS was well known, practiced and immediately envisaged at the time the invention was made in the art. In addition, the intended use or amount to elicit alloantigen specific hyporesponsiveness would have been met by the reference as such claimed amounts encompass a broad range as the amount of antibody to elicit said immunosuppression would depend on the nature of the system being analyzed or tested.

Rejection Under 35 U.S.C. § 103

Claims 30-43 stand rejected under 35 U.S.C. § 103 as being unpatentable over Xia et al. (Rat Hybridomas and Rat Monoclonal Antibodies, 1990) in view of Queen et al. (U.S. Patent No. 5,530,101) or Newman et al. (U.S. Patent No. 5,658,570) and in further view of Guckel et al. (J. Exp. Med., 1991) OR Bromberg et al. (Transplant., 1991) OR Hafler et al. (J. Immunol., 1988) OR Chavin et al. (Transplant., 1992) OR Faustman (U.S. Patent No. 5,283,058).

The instant claims are drawn to antibodies that bind the LO-CD2 specificity, including chimeric and humanized antibodies, as well as cell that produced said antibodies and methods of making said antibody.

Xia et al. provides a number of phenotypic and functional characteristics that are associated with the LO-CD2a specificity (see entire document). Also, Xia et al. distinguishes the LO-CD2a specificity from other CD2-specific antibodies and clearly discloses that this specificity binds a different epitope from other CD2-specific antibodies (for example, see page 320, paragraphs 1-3). It would have been expected at the time the invention was made that different antibodies would recognize the same conformational epitope, which is the LO-CD2 epitope in the instant case. The prior art clearly set forth numerous features that characterize and enable one of skill in the art at the time the invention was made to make an antibody that binds to the same LO-CD2 epitope specificity as claimed. Xia et al. Differs from the instant claims by not disclosing chimeric or humanized antibodies per se.

Queen et al. teaches the art-known procedures at the time the invention was made to produce chimeric antibodies starting from hybridoma and antibody producing cells (see entire document)..

Similarly, Newman et al. teach the generation of recombinant antibodies including CD2-specific antibodies for various diagnostic and therapeutic uses (see entire document).. While it is noted that Newman et al. teaches the use of Old World Monkey portions in the derivation of recombinant antibodies, this reference clearly recognizes the derivation of chimeric and humanized antibodies at the time the invention was made and that CD2 was a desired specificity at the time the invention was made.

One of ordinary skill in the art at the time the invention was made would have generated chimeric or humanized antibodies in order to reduce immunogenicity while retaining high binding affinity for diagnostic and therapeutic purposes as well as the appropriate vectors, host cells, etc. to accomplish the engineering of chimeric and humanized antibodies (see entire documents). Therefore, Queen et al. OR Newman et al. teach that immunoglobulin gene structure and organization were well understood in the art at the time the claimed invention was made and that strategies for cloning the DNAs encoding immunoglobulin variable regions genes were well established in the art at the time the claimed invention was made, as were methods for the production of DNA constructs comprising expression vectors containing DNAs encoding immunoglobulin variable regions. Queen et al. AND Newman et al. differ from the claimed invention by not teaching the LO-CD2a specificity per se, the ordinary artisan would have been motivated to apply the teachings of Queen et al. OR Newman et al. to enable the isolation and construction of chimeric and humanized antibodies that bind the LO-CD2a specificity.

In addition to the LO-CD2a specificity, the instant claims also encompass antibodies that elicit alloantigen specific unresponsiveness. Guckel et al., Bromberg et al., Hafler et al., Chavin et al. and Faustman all teach the art-known potent inhibition of immune responses by blocking or modulating T cell surface receptors such as CD2 that are important in adhesion receptor-signaling (see entire documents, particularly the Introductions and Discussions).

Guckel et al. teach the ability of rat anti-CD2 antibodies to induce T cell unresponsiveness in vivo in mice (see entire document). CD2-specific antibody inhibition of transplants and autoimmunity is taught (page 965, column 2, paragraph 2).

Bromberg et al. teach that anti-CD2 antibodies alter cell-mediated immunity in vivo by altering the array of cell surface receptors and subsequent responses to antigenic challenge (see entire document). Bromberg et al. also teach the potent immunosuppressive properties of anti-CD2 antibodies for murine allografts and xenografts as well as for primate skin and renal allografts (page 224, column 1, paragraph 1).

Hafler et al. teach that anti-CD2 antibodies inhibit T cell responses in human patients with progressive multiple sclerosis (see entire document). Hafler et al. also teach that T cell-specific antibodies have been used successfully as immunosuppressive reagents in transplant rejections and autoimmune diseases (see Introduction).

Chavin et al. teaches the efficacy of treating allografts and xenografts in vivo with CD2-specific antibodies (see entire document, particularly the Introduction and Discussion). Prolonged allograft survival correlated with suppression of both CTL and NK activity (page 290, column 1, paragraph 3 and Table 2). Here, Chavin et al. concludes by stating that the ability of anti-CD2 antibodies to suppress lymphocyte precursors and T and non-T cell responses supports its use for induction therapy in transplantation.

Faustman teaches methods of inhibiting the rejection of allografts and xenografts with T cell-specific antibodies and antibody fragments including the CD2-specificity (see entire document, including column 5, paragraph 1). Such methods of inhibiting rejection include modifying, eliminating and masking an antigen on the surface of a cell (see entire document, including Abstract).

It would have prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to generate CD2-specific antibodies including the LO-CD2-specific antibodies to characterize the CD2 specificity and to target said specificity for various biological, diagnostic and therapeutic modalities. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Rejection Under Obviousness-Type Double Patenting

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321 (b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

As indicated above and acknowledged by appellant; USSN 08/477,989 has issued as U.S. Patent No. 5,951,983.

Claims 30-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,951,983 (previously over copending application USSN 08/477,989). Although the conflicting claims are not identical, they are not patentably distinct from each other because because the patented claims are a species of the instant claims of antibodies that bind the same epitope as the LO-CD2 antibody.

Claims 30-43 are directed to an invention not patentably distinct from claims 1-4 of U.S. Patent No. 5,951,983. Specifically, the conflicting claims are patentably distinct from each other because the patented claims are a species of the instant claims of antibodies that bind the same epitope as the LO-CD2 antibody.

Commonly assigned U.S. Patent No. 5,951,983, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78© to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

Claims 30-44 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 18-19 U.S. Patent No. 5,730,979

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to same or similar LO-CD2-specific antibodies, including chimeric and humanized antibodies.

Appellant will consider filing a Terminal Disclaimer when the other rejections are reversed.

(11) Response to Argument

Rejection Under 35 U.S.C. § 102(b)

Appellant's arguments, in conjunction with the Bierer declaration under 37 C.F.R. § 1.132, have been fully considered but are not found convincing.

It is acknowledged that the issue remains as to whether or not, given the prior art teaching of Xia et al.; the ordinary artisan would be enable to obtain an antibody which binds to the same epitope as the antibody produced by the deposited cell line.

Appellant argues in conjunction with the Bierer declaration that during the prosecution of parent application USSN 08/472,281, now U.S. Patent No. 5,817,311, that one skilled in the art could not produce the deposited antibody and that, in turn, one skilled in the art would not be enabled by Xia to produce an antibody which binds to the same epitope.

It is noted that in USSN 08/472,281, now U.S. Patent No. 5,817,311; the method claims were allowed in view of the unexpected clinical properties of LO-CD2-specific antibodies disclosed in the specification. Successful treatment of transplant rejection including after the onset of rejection with CD2-specific antibodies was unobvious at the time the invention was made. Accordingly the claims of this application are deemed allowable

In contrast with antibody product claims; it is noted that in USSN 08/477,877 now U.S. Patent No. 5,730,979; the LO-CD2a produced by the ATCC HB 11423 was deemed structurally distinct on the primary amino acid basis due to high polymorphism of antibodies and therefore free from the prior art.

Therefore, the prosecution of appellant's priority documents distinguished prior art issues as they applied to antibody products and their methods of use.

Appellant argues that the characteristics which are defined in Xia are not characteristics which define a specific epitope, but rather address characteristics common to CD2 antibodies as a class.

Appellant argues that Xia does not identify the epitope which LO-CD2a antibody binds and does not provide the LO-CD2 antibody; it does not enable the claimed specificity.

Appellant asserts that even if one skilled in the art were able to identify an antibody which had characteristics similar to those of the LO-CD2a antibody disclosed in Xia et al., such characteristics do not indicate whether or not an antibody binds to the same epitope as the deposited antibody in that such characteristics are those generally possessed by CD2 antibodies.

Appellant argues in conjunction with Bierer that one skilled in the art would have no way of knowing which, if any of the antibodies which would be produced by the general procedure disclosed by Xia et al. is LO-CD2a or which binds to the same epitope as the antibody of the present invention in that the characteristics disclosed by Xia et al. do not define LO-CD2a uniquely, that is, do not distinguish LO-CD2a from CD2 antibodies as a class or define which antibodies binds to the same epitope as LO-CD2a or deposited antibody.

Therefore, appellant concludes that Xia et al. does not disclose nor render obvious antibody that bind the same epitope as the antibody produced by the deposited cell line.

Appellant acknowledges that page 320 of Xia et al. indicates that LO-CD2a antibody binds to an epitope which is different from other antibodies referred to on page 320; appellant argues that Xia does not identify or define the epitope which LO-CD2a binds.

Appellant argues that Xia et al. does not make LO-CD2a available to the ordinary artisan and that the ordinary artisan would not have enough information to determine whether or not a produced antibody bound to the same epitope.

Appellant asserts that at best, the prior art permits the ordinary artisan to determine that a produced antibody is not D66.

Further, appellant argues that prior art does not provide reasonable expectation of success that the claimed antibody or a composition comprising said antibody could be used successfully in humans. Appellant asserts that the prior art as a whole suggest that CD2 antibody would not be successful.

Appellant relies upon Thurlow et al. (Transplant., 1983) and Giorgi et al. (Transplant. Proc., 1983) indicated that anti-CD2 antibodies were not successful in primate or human studies.

Appellant relies upon the instant disclosure to show the success of the LO-CD2 antibody in human treatment.

In addition, appellant have found unexpectedly that the claimed antibody may be employed to treat humans, contrary to the wisdom of the prior art. Therefore there is a clear indication of the nonobviousness of the claimed antibody as employed in combination with an acceptable carrier for treating humans.

Appellant asserts that the prior art does not disclose or remotely suggest to the ordinary artisan that the claimed antibody may be used to treat humans, the cited prior art does not render obvious to one of ordinary skill in the art that the combination of the claimed antibody and an acceptable carrier as defined in Claim 38, even if , assuming solely for the sake of arguments the claimed antibody was known.

Evidence of secondary considerations such as unexpected results is irrelevant to 35 U.S.C. § 102 rejections and thus cannot overcome a rejection so based. See MPEP 2131.04

In addition, the claims are drawn to product claims and do not require the ability to treat humans. Even in those claims which recite functional properties (e.g. claims 37-43); the claimed recitation simply encompasses the ability to inhibit a T cell mediated immune response or to elicit alloantigen specific hyporesponsiveness by the claimed antibodies. In addition to the inherency of the prior art antibodies; the claimed functional limitations may be met either in vitro or in vivo and are not limited to effects as they read on inhibiting human transplant rejection.

Also, in contrast to appellant's assertions that the it is virtually impossible to treat within 24 hours of antigen priming; there are certain situation such as transplantation or experimental culture systems, wherein the ordinary artisan knows when antigen is provide and, in turn, would provide antagonistic anti-CD2 antibodies, including LO-CD2a-specific antibodies.

While appellant may be relying upon the intended use of the claimed antibodies to induce antigen specific hyporesponsiveness; the intended use or amount to elicit alloantigen specific hyporesponsiveness was met by the prior art as such claimed functional properties encompass a broad range of activities and a broad range of antibody amounts to elicit immunosuppression depending on the nature of the system being analyzed or tested.

Appellant asserts that the totality of the references, including the Bierer Declaration indicate that the characteristics disclosed by Xia et al. are not sufficient to identify LO-CD2 in a manner that distinguishes LO-CD2 from CD2 antibodies as a class or enables the ordinary artisan to identify antibodies which binds to the same epitope as the antibody produced by the deposited cell line.

In contrast to appellant's arguments, Xia et al. teach the LO-CD2a-specificity and rely upon a number of characteristics to distinguish this specificity (see entire document, including Tables 1-6 and Figures 1-4), including distinguishing the LO-CD2 specificity from other CD2-specific antibodies (see page 320, paragraphs 1-3).

Here in Xia et al.; the Tables and Figures provide for a profile of binding specificities and functional properties both in a quantitative and qualitative manner. For example, Tables 1-4 and Figures 1-4 provide for reactivity patterns of antibodies that provide for intensity of binding in addition to binding specificity.

Here, the LO-CD2 antibody specificity is compared with another anti-CD2 antibody specificity, namely the OKT11/T11 antibody (See Tables and Figures).

Xia et al. discloses that reactivity patterns of LO-CD2 antibody and OKT11 exhibit similarities; they are not considered identical. See page 320, paragraph 1.

Here, the difference between LO-CD2 and OKT11 is that LO-CD2 always show a weaker reaction with T lymphocytes than T11 and that LO-CD2 did not react with T cell line CEM, while OKT11 did.

Xia et al. distinguish the epitope recognized by another CD2 antibody, namely D66, based upon functional characteristics of blocking E-rosette formation. See page 320, paragraph 2.

LO-CD2 was also compared with non-CD2-specific antibodies, wherein the effect of LO-CD2 was in sharp contrast to that of CD25-specific antibodies. See page 320, paragraph 4.

Section 4 of the Bierer Declaration. asserts that reactivity patterns in Figures 1A/1B is not statistically different from another CD2 antibody, namely OKT11.

However, as pointed out above; Xia et al. do not rely upon Figures 1A/1B alone to distinguish LO-CD2 from OKT11. Here, the difference between LO-CD2 and OKT11 is that LO-CD2 always show a weaker reaction with T lymphocytes than T11 and that LO-CD2 did not react with T cell line CEM while OKT11 did.

Section 16 of the Bierer Declaration relies upon the Third International Workshop and Conference on Human Leukocyte Differentiation Antigens, 1986 (page 149) to indicate that several CD2 antibodies which did not react with CEM cells, did react with MOLT4 cells, HPB-ALL cells and Jurkat cells, whereby the reactivity patterns of Table 4 is not unique to LO-CD2.

It appears that even among these CD2-specific antibodies referred to Table 1 (page 149) of the Third International Workshop; these antibodies do not have the same or identical characteristic profiles that these profiles can be distinguished from all of the characteristics of the LO-CD2a-specificity set forth in Xia et al.

Again, it is the totality of the reactivity patterns and functional characteristics clearly disclosed in Xia et al. that serves to distinguish the LO-CD2 antibody specificity over the prior art and not just binding to one cell line or even a few binding characteristics.

Given all of the criteria of the anti-LO-CD2 antibody specificity clearly taught and enabled by the prior art Xia et al. teaching; the ordinary artisan would have been enabled to making and using antibodies which bind the same LO-CD2a epitope encompassed by the claimed invention.

While the characteristics disclose by the prior art may be common to certain classes of CD2-specific antibodies, this reference clearly distinguishes the LO-CD2 antibody specificity from other CD2-specific antibodies, including providing a profile of a number of characteristics and comparisons for antibodies that bind the same epitope as the LO-CD2a antibody.

Therefore, claims 30-32, 35-40 and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Xia et al. (Rat Hybridomas and Rat Monoclonal Antibodies, 1990).

Appellant's arguments are not found persuasive.

Rejection Under 35 U.S.C. § 103

Appellant's arguments have been fully considered but are not found persuasive essentially for the reasons of record and set forth above in the rejection under 35 U.S.C. § 102(b).

As pointed out above; it is the totality of the reactivity patterns and functional characteristics clearly disclosed in Xia et al. that serves to distinguish the LO-CD2 antibody specificity over the prior art and not just binding to one cell line or even a few binding characteristics.

Given all of the criteria of the anti-LO-CD2 antibody specificity clearly taught and enabled by the prior art Xia et al. teaching; the ordinary artisan would have been enabled to making and using antibodies which bind the same LO-CD2a epitope encompassed by the claimed invention.

While the characteristics disclose by the prior art may be common to certain classes of CD2-specific antibodies, this reference clearly distinguishes the LO-CD2 antibody specificity from other CD2-specific antibodies, including providing a profile of a number of characteristics and comparisons for antibodies that bind the same epitope as the LO-CD2a antibody.

With respect to appellant's assertions of unexpected results as it would read on the rejection under 35 U.S.C. § 103 rather than 35 U.S.C. § 102(b); the following from above is noted as well.

Appellant argues that prior art does not provide reasonable expectation of success that the claimed antibody or a composition comprising said antibody could be used successfully in humans. Appellant asserts that the prior art as a whole suggest that CD2 antibody would not be successful.

Appellant relies upon Thurlow et al. (Transplant., 1983) and Giorgi et al. (Transplant. Proc., 1983) indicated that anti-CD2 antibodies were not successful in primate or human studies.

Appellant relies upon the instant disclosure to show the success of the LO-CD2a antibody in human treatment.

In addition, appellant have found unexpectedly that the claimed antibody may be employed to treat humans, contrary to the wisdom of the prior art . Therefore there is a clear indication of the nonobviousness of the claimed antibody as employed in combination with an acceptable carrier for treating humans.

Appellant asserts that the prior art does not disclose or remotely suggest to the ordinary artisan that the claimed antibody may be used o treat humans, the cited prior art does not render obvious to one of ordinary skill in the art that the combination of the claimed antibody and an acceptable carrier as defined in Claim 38, even if , assuming solely for the sake of arguments the claimed antibody was known.

In addition, the claims are drawn to product claims and do not require the ability to treat humans. Even in those claims which recite functional properties (e.g. claims 37-43); the claimed recitation simply encompasses the ability to inhibit a T cell mediated immune response or to elicit alloantigen specific hyporesponsiveness by the claimed antibodies. In addition to the obviousness of the prior art antibodies, including chimeric or humanized antibodies; the claimed functional limitations may be met either in vitro or in vivo and are not limited to effects as they read on inhibiting human transplant rejection.

Also, in contrast to appellant's assertions that it is virtually impossible to treat within 24 hours of antigen priming; there are certain situation such as transplantation or experimental culture systems, wherein the ordinary artisan knows when antigen is provide and, in turn, would provide antagonistic anti-CD2 antibodies, including LO-CD2a-specific antibodies.

While appellant may be relying upon the intended use of the claimed antibodies to induce antigen specific hyporesponsiveness; the intended use or amount to elicit alloantigen specific hyporesponsiveness was met by the prior art as such claimed functional properties encompass a broad range of activities and a broad range of antibody amounts to elicit immunosuppression depending on the nature of the system being analyzed or tested. Further, appellant's reliance on unexpected results do not overcome clear and convincing evidence of obviousness.

It would have prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to generate CD2-specific antibodies including the LO-CD2-specific antibodies to characterize the CD2 specificity and to target said specificity for various biological, diagnostic and therapeutic modalities. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 30-43 stand rejected under 35 U.S.C. § 103 as being unpatentable over Xia et al. (Rat Hybridomas and Rat Monoclonal Antibodies, 1990) in view of Queen et al. (U.S. Patent No. 5,530,101) or Newman et al. (U.S. Patent No. 5,658,570) and in further view of Guckel et al. (J. Exp. Med., 1991) OR Bromberg et al. (Transplant., 1991) OR Hafler et al. (J. Immunol., 1988) OR Chavin et al. (Transplant., 1992) OR Faustman (U.S. Patent No. 5,283,058).

Appellant's arguments are not found persuasive.

Rejection Under Obviousness-Type Double Patenting

Appellant will consider filing a Terminal Disclaimer when the other rejections are reversed.

(12) For the above reasons, it is believed that the rejections should be sustained.

Respectively submitted,

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August 21, 2000

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